

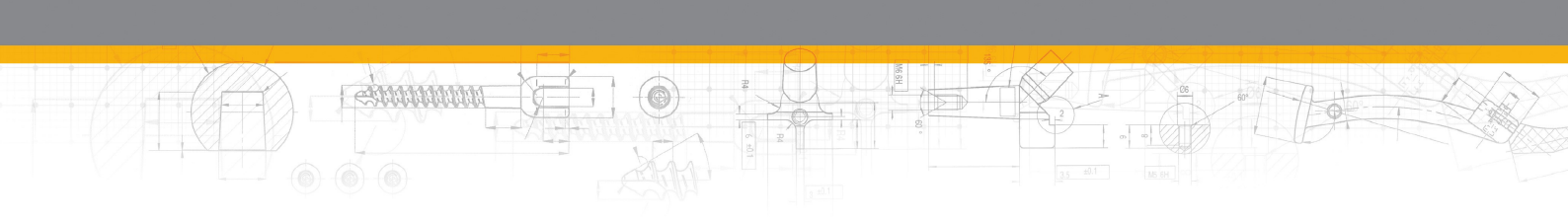


BIOTECHNI®

FILLER-3ND AND FEMORAL HEADS

CEMENTLESS & CEMENTED FEMORAL STEMS
STAINLESS STEEL AND BIOLOX® DELTA FEMORAL HEADS
SURGICAL TECHNIQUE





Design

The **Femoral Stems of the FILLER-3ND range** are available with and without hydroxyapatite coating. Its concept collects and combines the technical developments which have sufficient hindsight in the hip arthroplasty for more than 30 years.

The design geometry of the cementless stem gives the primary mechanical stability while the Hydroxyapatite (HA) coating allows secondary biological integration. The combination of the design and the HA coating facilitates implantation and ensures strong stability. The "Mini-Taper" neck minimizes the conflict with the acetabular component (dual mobility in particular) when the used head has a short or medium neck.

Femoral heads have sphericity and surface roughness in compliance with ISO 7206-2. They are available in taper 12/14. They are compatible with all Biotechni's femoral stems.

BIOLOX®*delta* heads are manufactured and delivered by CeramTec. A Biolox®*delta* head must be associated with a BIOLOX®*delta* insert. The BIOLOX®*delta* head is used for a primary arthroplasty.

Materials

The cementless stems are manufactured from Titanium Alloy (Ti6Al4V) in compliance with 5832-3 and ASTM F136 standards. The coating used for the stem is made of Titanium (Y 368) and hydroxyapatite (K 630). Both materials are biocompatible and comply with ISO 13779-2, ASTM F 1580 and ASTM F1185 standards.

The cemented stems are manufactured from Stainless Steel in compliance with ISO 5832-9 standard.

The stainless steel femoral heads are made of wrought high nitrogen stainless steel according to the ISO 5832-9 and ASTM F1586 standards.

BIOLOX®*delta* is an aluminum oxide matrix composite ceramic consisting of approximatively 82% alumina (Al₂O₃), 17% zirconia (ZrO₂) and other trace elements. The pink color is due to the chromium oxide (Cr₂O₃).

Indications

- Femoral head or neck fractures (cemented and cementless versions);
- Aseptic osteonecrosis of the femoral head (cementless version);
- Arthrosis (cemented and cementless versions);
- Rheumatoid arthritis and post-traumatic arthritis (cementless version).;
- Total replacement of articular hip prosthesis (cementless version);
- Partial replacement of articular hip prosthesis (cementless version, except for Biolox®*delta* femoral head);

The implants are intended to be used on adult patients (skeletally mature).

Contraindications

Conditions which can severely affect the success of the implantation:

- Any local, acute, or chronic infection. Any infectious illness. Fever or leucocytosis.
- Systemic and metabolic disorders. Any mental or neuromuscular disorder.
- Deficient bone stock, osteopenia and/or severe osteoporosis.
- Drug, tobacco and/or alcohol addiction and/or abuse.
- Intense physical activity.
- Proved or suspected sensitivity to materials.
- Tumor unresectable or residual.
- Non terminated skeletal development.
- Pregnancy, obesity or overweight (BMI >25).

These contraindications are of general order and not exhaustive, and the surgeon will have to evaluate each patient, in order to determine the risks specific to the surgery and the benefit for the patient.

Sizes

Each model offers 11 sizes: from 9 to 20 (lengths 130 to 190mm) covering all the requirements of primary arthroplasty.

BIOLOX®*delta* and Stainless-Steel head are available in taper 12/14 and in various diameters with different neck lengths.

Preoperative planning

Whatever arthroplasty is chosen (hemiarthroplasty or total hip replacement), the procedure should be carefully planned with sufficient detail. Select the prosthesis with the aid of radiographic templates and appropriate x-rays of the normal and injured hip.

Surgical technique

Step 1 Femoral neck osteotomy

The operation begins with adequate exposure of the fracture site through a sufficient capsular incision.

The 130° angle of the cut is determined with the **cutting guide** (ref.C15A-150).



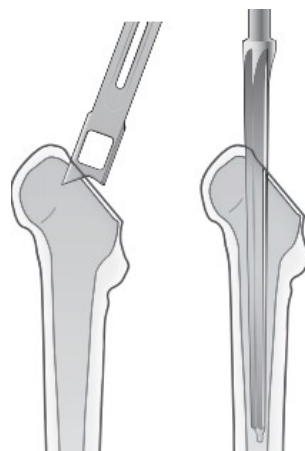
Step 2 Femoral canal preparation

Remove remnants of the femoral neck and open the medullary canal.

It is recommended to dig the armpit of the greater trochanter using a **chisel** (ref. C15A-140) which corresponds to the antero-posterior dimensions of the femoral stem. This will avoid the risk of valgus or varus during the implementation of the final femoral stem.

To make easier the insertion of the rasp, the initial **reamer Ø8** (ref. C15A-132) and the **conical reamer** (ref. C15A-120) can be successively used.

The angled face of the rasp must be flush with the previous cut level.



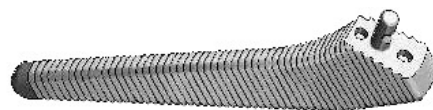
Use of the rasps



Rasp handle guide
(ref. CA-ER101)



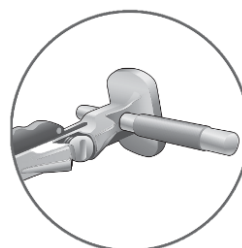
Spike rasp
(ref. RA-96xx)



Compactor rasp
(ref. RA-95xx)



Rasp handle (ref. CMA-950)



Rasp handle with guide

Femoral reaming

Introduce the rasps successively in the axis of the femur until obtaining a perfect stability.

If required, the **rasp handle guide** (ref. CA-ER101) can be used to improve the stability and the guidance of the rasp handle.



Calcar preparation (optional)

After the introduction of the last rasp, it is possible to improve to achieve a flat resection surface using the **calcar reamer** (ref. C15A-160).

T-handle (ref. A042-2000) is recommended.

Note: ream slowly to prevent the calcar cracking and any tissue.

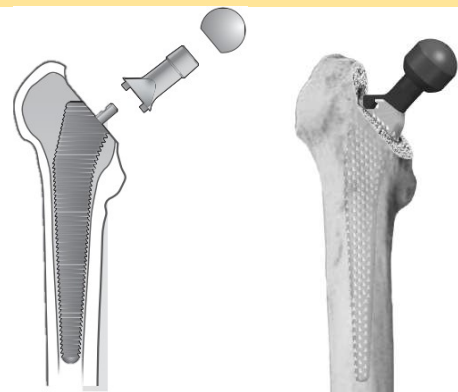


Step 3 Trial implants

After calcar reaming, stay the last rasp in place in the femur. Place the desired **trial neck** (ref. C5T-1xx) matching with the stem, then trial **femoral head** (ref. Txx5yy) on the trial neck and reduce the hip to assess stability and range of motion.

For cementless stems, the size of last rasp match with the size of the final stem (for example rasp 11 = stem size 11).

For cemented stems, we recommend to choose the final stem having two sizes under the last rasp (for example rasp 11 = stem size 9).



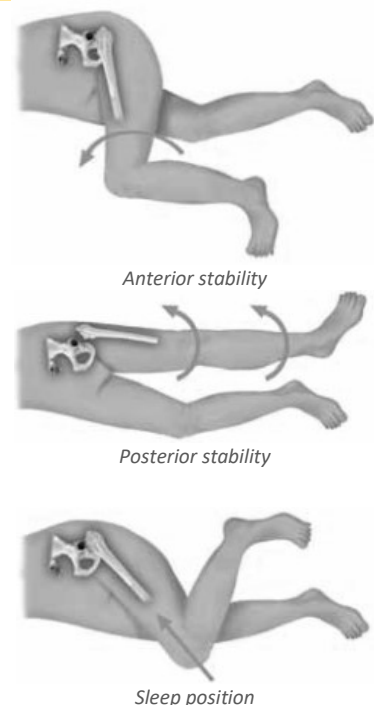
Step 4 Trial reduction

Reduce the hip and evaluate in the following ways:

-anterior stability: place the leg in full adduction and hyperextension, while exerting an external rotation force. If the hip cannot be fully extended, it may be too tight. If it dislocates easily, it is too loose and impingement must be addressed or component malposition exists.

-posterior stability: place the leg in adduction and 90° flexion. Gradually rotate internally. The hip should be stable with 45° of internal rotation. If it dislocates with minimal internal rotation, it is too loose and impingement must be addressed or component malposition exists.

-sleep position: place the leg in the “sleep position” with the operated leg semi-flexed, adducted and internally rotated over the other leg. Apply axial force to try to dislocate. This position represents a dangerously unstable position that may be adopted by a patient sleeping on their non-operated side.



Step 5 Stem insertion

Cementless stem insertion

After having the rasp removed, clean the femoral cavity.

The stem is screwed on the **stem holder handle** (ref. C4A-SI101) and locked using the spanner. The insertion of the stem is stopped at the level marked on the implant (limit of the hydroxyapatite coating).

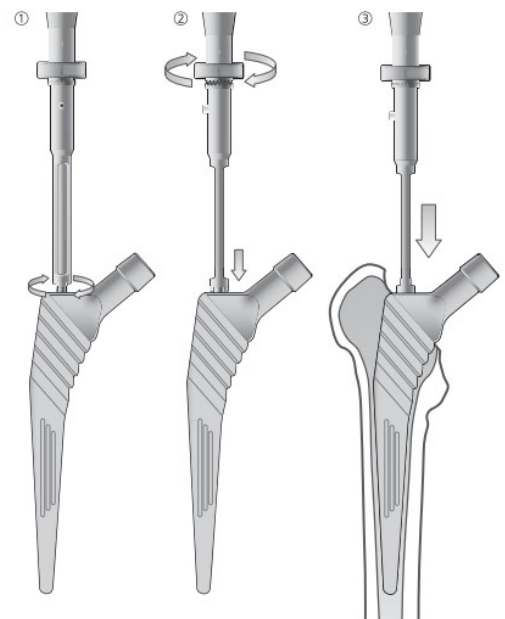
When the stem is impacted, unscrew the stem holder after the spanner had been unlocked.

Once the stem is fully seated, perform a final trial reduction to determine appropriate neck length. Place the desired femoral head on the implant and reduce the hip to assess stability and range of motion.

Cemented stem insertion

The cemented stem is placed into the femoral canal and pushing with the special **stem impactor** (ref. C4A-SI202) till the laser mark on the stem.

(The stem impactor allows the antero- or retroversion of the stem into the cement).



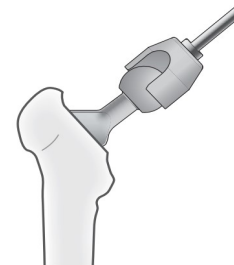
Step 6 Femoral head insertion

Carefully clean and dry the cone femoral stem before implementing the final head.

Place the prosthetic femoral head on the neck taper and firmly impact with a femoral **head impactor** (ref. CA-PH00) and a **basic hammer** (ref. C15A-100).

A small hit on the **head pusher** (ref. C4A-ETxx) is also possible to achieve the impaction of the head.

To verify fixation of the head, attempt to remove the head by hand. No movement shall be perceptible.



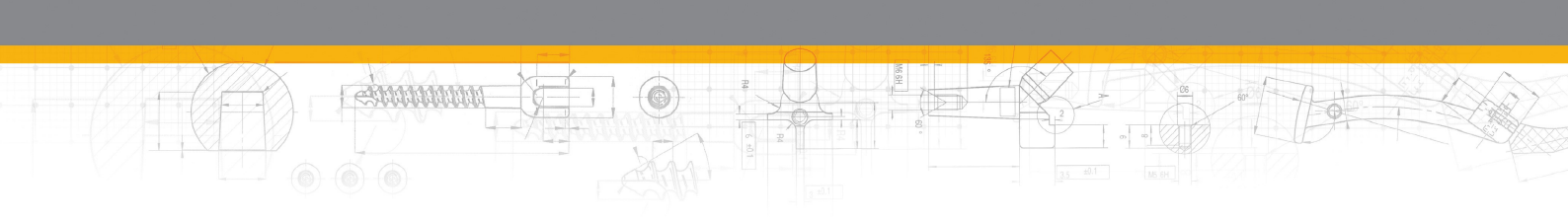
As part of an implantation of a ceramic head, the stem taper and the inner taper of the BIOLOX® ball head have to be inspected carefully before assembly and any foreign bodies such as tissue parts, bone or cement particles must be removed.

The BIOLOX® ball head has to be fixed on the stem taper by using slight axial pressure and twisting at the same time.

Afterwards, the plastic head impactor has to be placed on the pole of the BIOLOX® ball head, and with one or several moderate strikes of the hammer on the plastic head impactor in alignment with the ball head axis, the BIOLOX® ball head is fixed on the stem taper.

Caution: The BIOLOX® ball head must never be directly struck with a hammer. Never use a metallic tipped instrument. Only





the plastic head impactor provided for this purpose by BIOTECHNI may be used.

Step 7 Reduction

Prior to reduction, wash correctly throughout the joint. Using the head pusher, reducing overall in the acetabulum.

Check the stability of the assembly and close the wound.

FILLER-3ND femoral stems range

FILLER-3ND 135° Ti+HA coated	
FI04009	size 09
FI04010	size 10
FI04011	size 11
FI04012	size 12
FI04013	size 13
FI04014	size 14
FI04015	size 15
FI04016	size 16
FI04018	size 18
FI04020	size 20

FILLER-3ND Ti coated	
FI05009	size 09
FI05010	size 10
FI05011	size 11
FI05012	size 12
FI05013	size 13
FI05014	size 14
FI05015	size 15
FI05016	size 16
FI05018	size 18
FI05020	size 20

FILLER-3ND Ti+HA coated With collar	
FIC04009	size 09
FIC04010	size 10
FIC04011	size 11
FIC04012	size 12
FIC04013	size 13
FIC04014	size 14
FIC04015	size 15
FIC04016	size 16
FIC04018	size 18
FIC04020	size 20

FILLER-3ND Stainless Steel Cemented	
FI04109	size 09
FI04110	size 10
FI04111	size 11
FI04112	size 12
FI04113	size 13
FI04114	size 14
FI04115	size 15
FI04116	size 16
FI04118	size 18
FI04120	size 20

FILLER-3ND 130 ° varised Ti+HA coated	
FI04309	size 09
FI04310	size 10
FI04311	size 11
FI04312	size 12
FI04313	size 13
FI04314	size 14
FI04315	size 15
FI04316	size 16
FI04318	size 18
FI04320	size 20

FILLER-3ND 130 ° lateralized Ti+HA coated	
FI04409	size 09
FI04410	size 10
FI04411	size 11
FI04412	size 12
FI04413	size 13
FI04414	size 14
FI04415	size 15
FI04416	size 16
FI04418	size 18
FI04420	size 20

Stainless Steel femoral head range

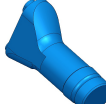
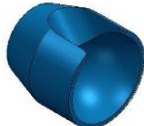
$\varnothing$	Neck size	Reference
22.22 mm	Short (-4)	IN22.005
	Medium (0)	IN22.010
	Long (+4)	IN22.015
28 mm	Short (-3.5)	IN28.005
	Medium (0)	IN28.010
	Long (+3.5)	IN28.015
	Extra-long (+7)	IN28.020

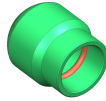
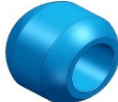
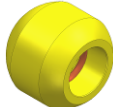
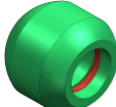
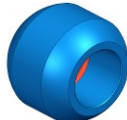
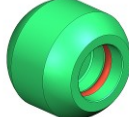
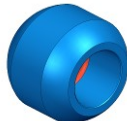
BIOLOX[®] delta femoral head range

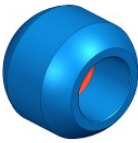
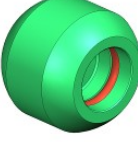
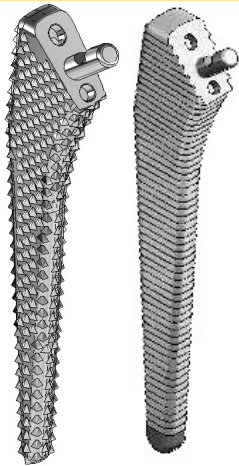
$\varnothing$	Neck size	Reference
28 mm	Short (-3.5)	CER285-05
	Medium (+0)	CER285-10
	Long (+3.5)	CER285-15
32 mm	Short (-4)	CER325-05
	Medium (+0)	CER325-10
	Long (+4)	CER325-15
	Extra-long (+7)	CER325-20
36 mm	Short (-4)	CER365-05
	Medium (+0)	CER365-10
	Long (+4)	CER365-15
	Extra-long (+8)	CER365-20
40 mm *	Short (-4)	CER405-05
	Medium (+0)	CER405-10
	Long (+4)	CER405-15
	Extra-long (+8)	CER405-20
* available upon request		

Instruments

Reference	Designation	Picture
ANC-HANCHE-FILLERFORTRESS-950	Container with removable tray and lid	
ANC-HANCHE-FILLERFORTRESS-960		
C15A-100	Basic hammer	
C15A-150	Cutting guide 130°	
A042-2000	T-handle for connection AO	
CA-ER101	Rasp handle guide	
C4A-SE300	Stem extractor	
C4A-SE301	Weight for hammer	
C4A-SI101	Stem holder handle	
CA-PH00	Head pusher holder	
C4A-SI202	Special steerable impactor handle	

Reference	Designation	Picture
CMA-950	Rasp handle	
C15A-120	AO connection conical Starter reamer	
C15A-132	AO connection initial reamer Ø8 mm	
C15A-110	Femoral head extractor for AO connection	
C15A-140	Chisel	
C15A-160	AO connection calcar reamer Ø36	
C5T-130L	Lateralized trial neck 130° (5°42'30")	
C5T-130V	Varised trial neck 130° (5°42'30")	
C5T-135S	Standard trial neck 135° (5°42'30")	
C4A-ET22	Head pusher Ø 22	
C4A-ET28	Head pusher Ø28	
C4A-ET32	Head pusher Ø32	
C4A-ET36	Head pusher Ø36	
T225CC	Trial head 5°43'30" Ø22.22 mm (-4)	
T225CM	Trial head 5°43'30" Ø22.22 mm (0)	

Reference	Designation	Picture
T225CL	Trial head 5°43'30" Ø22.22 mm (+4)	
T285CC	Trail head 5°43'30" Ø28 col court (-3.5)	
T285CM	Trial head 5°43'30" Ø28 mm (0)	
T285CL	Trial head 5°43'30" Ø28 mm (+3.5)	
T285XL	Trial head 5°43'30" Ø28 mm (+7)	
T325CC	Trial head 5°43'30" Ø32 mm (-4)	
T325CM	Trial head 5°43'30" Ø32 mm (0)	
T325CL	Trial head 5°43'30" Ø32 mm (+4)	
T325XL	Trial head 5°43'30" Ø32 mm (+7)	
T365CC	Trial head 5°43'30" Ø36 mm (-4)	
T365CM	Trial head 5°43'30" Ø36 mm (0)	
T365CL	Trial head 5°43'30" Ø36 mm (+4)	
T365XL	Trial head 5°43'30" Ø36 mm (+8)	

Reference		Designation	Picture
T405CC*		Trial head 5°43'30" Ø40 mm (-4)	
T405CM*		Trial head 5°43'30" Ø40 mm (0)	
T405CL*		Trial head 5°43'30" Ø40 mm (+4)	
T405XL*		Trial head 5°43'30" Ø40 mm (+8)	
RA9608	RA9508J	Rasp size 08	
RA9609	RA9509J	Rasp size 09	
RA9610	RA9510J	Rasp size 10	
RA9611	RA9511J	Rasp size 11	
RA9612	RA9512J	Rasp size 12	
RA9613	RA9513J	Rasp size 13	
RA9614	RA9514J	Rasp size 14	
RA9615	RA9515J	Rasp size 15	
RA9616	RA9516J	Rasp size 16	
RA9618	RA9518J	Rasp size 18	
RA9620	RA9520J	Rasp size 20	
Choosing the type of rasp (spike rasp or compactor rasp) in the container * Available upon request for 40mm size BIOLOX®delta heads.			RA96xx: Spike rasp RA95xx: Compactor rasp

Before using the device, the Orthopaedic surgeon must refer to the Instructions for Use, Package Insert and/or product label.

Thank you for sending us your suggestions to:

BIOTECHNI Z.I. Athélia II
 178, avenue du Serpolet
 13600 La Ciotat - France
 Tél. : + 33 (0)4 42 98 14 30
 Fax : + 33 (0)4 42 98 14 39
 E-mail : regulatory@biotechni.com